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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/648,490	08/25/2000	Robert R. Whittle	5573-124	5616

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EXAMINER

KWON, BRIAN YONG S

ART UNIT	PAPER NUMBER
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1614

DATE MAILED: 12/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/648,490

Applicant(s)

WHITTLE ET AL.

Examiner

Brian S Kwon

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 August 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 3-7 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 3-7 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Summary of Action

- I. The rejection of the claims 3-6 under 35 USC 112, second paragraph, is not maintained in light of the amendment.
- II. The rejection of the claims 3-6 under 35 USC 102(a) as being anticipated by Junggren is maintained for the reason of the record.
- IV. The rejection of the claims 3-6 under the judicially created doctrine of double patenting over claims 19 to 29 and 32-34 of US'087 is maintained for the reason of the record.
- V. Applicant's amendment necessitates a new ground of rejection(s) in this Office Action.

Status of Application

1. By Amendment filed August 03, 2004, Claim 3 has been amended and claim 7 has been newly added. Claims 3-7 are currently pending for the prosecution on the merits.

New Matter

2. The amendment filed August 03, 2004 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: Omeprazole composition "fixed with a ratio from about 11% or more 5-methoxy and from about 89% or less 6-methoxy".

Although applicant states that support for the claim 7 can be found on page 8, line 14 to page 12, line 13, however, careful reviewing of the specification reveals that there is no such support.

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The specification discloses approximately 0% 5-methoxy (standard 1); 4-6% 5-methoxy (standard 2); 7-8% 5-methoxy (standard 3); 11-13% 5-methoxy (standard 4); 15-17% 5-methoxy (standard 5-6); and 40-50% 5-methoxy (standard 7).

It is understood that the claimed ratio "from about 11% or more 5-methoxy and from about 89% or less 6-methoxy" refers to "from about 11% to about 89% of 5-methoxy isomer" and "from about 11% to about 89% of 6-methoxy isomer", such that the sum of two isomers equals 100%. In other words, the concentration of 5-methoxy isomer lies in range of "10.9, 11.0, 12.0, 13.0, 14.0...88.9, 89.0%" while the concentration of 6-methoxy isomer lies in range of "89.0, 88.0, 87.0...11.0, 10.9%" to make the sum of two isomers 100%.

As mentioned in preceding comments, the instant specification where applicant refers to as the basis for "fixed with a ratio from about 11% or more 5-methoxy and from about 89% or less 6-methoxy" fails to provide sufficient support for the newly added material in the claim 7.

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 4-5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 4 recites the limitation "a ratio of from about 11 percent or less 5-methoxy and from about 89 percent or more 6-methoxy" in claim 3 wherein claim 5 recites the limitation "a

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ratio of from about 17 percent or more 5-methoxy and from about 83 percent or less 6-methoxy” in claim 3. There is insufficient antecedent basis for these limitations in the claim.

Independent claim 3 recites that the claimed ratio falls within the range of “from about 5% or less of the 5-methoxy isomer and from about 95% or more of the 6-methoxy isomer”. In other words, the claimed concentration of 5-methoxy isomer lies within the range of “5.2, 5.1, 5.0...0.0%” while the concentration of 6-methoxy isomer lies within the range of “95.2, 95.1, 95.0...5.2, 5.1, 5.0%”. However, the claimed ratios in the dependent claims 4-5, for example “11.2, 11.1, 11.0...0.0%” of 5-methoxy and “89.2, 89.1, 89.0...11.2, 11.1, 11.0%” of 6-methoxy in claim 4 and “16.8, 16.9, 17.0...82.8, 82.9, 83.0%” of 5-methoxy and “83.0, 82.9, 82.8...17.0, 16.9, 16.8%” of 6-methoxy in claim 5 does not necessarily fall within the claimed ratio of the claim 3 and these inconsistencies lead to lack of clarity of the claims as a whole.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

4. Claims 3-4 and 6 are rejected under 35 U.S.C. 102(a) as being anticipated by Junggren et al. (US 4255431).

Junggren teaches a composition comprising 2-[2-(3,5-dimethyl-4-methoxy)-pyridylmethylsulfinyl]-(5-methoxy)-benzimidazole (omeprazole), wherein said omeprazole is formulated in various dosage forms (claim 20; column 5, line 59 thru column 7, line 18).

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Although Junggren is silent about "fixed with ratio of 5-methoxy and 6-methoxy isomer" or "fixed with a ratio of from about 11 percent or less 5-methoxy and from about 89% or more 6-methoxy" or "a predetermined ratio of 5-methoxy and 6-methoxy", such ratio must be inherently present in the composition, i.e., it was always there. Since 5-methoxy and 6-methoxy isomers is presented in $7:93 \pm 2\%$ in omeprazole or commercially available Prilosec (page 5, lines 6-7 and page 18, lines 10-14 of the specification), the referenced composition containing omeprazole "metes and bounds" the claimed invention. Therefore, the reference anticipates the claimed invention.

It is noted to applicant that the fact that applicant may have discovered a new property of omeprazole where omeprazole further comprises 6-methoxy in addition to known 5-methoxy fails to confer patentability to an old composition since such property or characteristic must be inherently present in the old composition. Therefore, the reference anticipates the claimed invention.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

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5. Claims 3-7 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 18-29 and 32-34 of U.S. Patent No. 6,369,087.

This rejection is analogous to the original rejection.

6. Claims 3-7 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-5 of US 6,268,385, claims 9-16 of US 6,262,086, claims 1-30 of US 6,653,329 and claims 1-4 of US 6,667,324. In looking in continuity data, it is noted that applicant has numerous issued patent and pending application encompassing the same or similar subject matter of the instant application. Applicant is aware of the patent and application is requested. Applicant review all subject matter considered same or similar, and submit the proper Terminal Disclaimer(s). For example, claims 1-5 of US 6,268,385, claims 9-16 of US 6,262,086, claims 1-30 of US 6,653,329 and claims 1-4 of US 6,667,324. The examiner's time to write each and every rejection is extremely burdensome.

Response to Arguments

7. Applicant's arguments filed August 03, 2004 have been fully considered but they are not persuasive.

In response to the rejection of the claims under the judicially created doctrine of double patenting over claims 19 to 29 and 32-34 of US'087, applicants allege that the double patenting rejections based on 35 USC 101 is improper and should be withdrawn. Applicants' argument takes position that distinct from the language of the claims of the US'087 (where the cited patents does not recite that the pharmaceutical formulation is fixed and determined by Fourier Transform Raman Spectroscopy", claims 3 of the present application does not recite diastereomers, metal cations or one to one ratios, therefore, independent claim 3 and claims 4-6

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of the present application which depend from claim 3, are not the "same invention" as that defined by claims 19 to 29 and 32-34 of US'087.

It is noted to applicant that the instant double patenting rejection is not based on 35 USC 101 statutory rejection. Rather, it is non-statutory obvious-type double patenting rejection. In other words, this rejection does not require "same invention" or "identical subject matter" as the applicant alleged. Apparently applicants have discussed the disagreeing arguments based on the incorrect standard, 35 USC 101.

The determination of amounts of known active ingredients in a composition having optimum therapeutic index is well considered within the skill of the artisan, and the artisan would be motivated to determine optimum amounts of the active ingredients to maximize the therapeutic effectiveness of the drug. Furthermore, since the individual isomers are obvious variants over the corresponding racemate because of their presence in the racemate. In absence showing unexpected or unobvious nature of the claimed invention, the examiner maintains that the reference makes obvious the claimed invention.

The examiner pointed out in the previous O.A. (Page 4) mailed May 20, 2004, that there are numerous patent and pending application encompassing the same or similar subject matter of the instant application, especially 1-5 of US 6,268,385, claims 9-16 of US 6,262,086, claims 1-30 of US 6,653,329 and claims 1-4 of US 6,667,324. However, applicants have not submitted any argument with respect to the issue. Applicant should submit an argument under the heading "Remarks" pointing out disagreements with the examiner's contentions. Applicant must also discuss the references applied against the claims, explaining how the claims avoid the references or distinguish from them.

In response to the rejection of the claims under 35 USC 102(a), the applicants' argument takes position that Junggren only discloses a 5-methoxy isomer and does not disclose a 6-methoxy isomer, Junggren could never have produced a pharmaceutical formulation with a predetermined ratio of 5- and 6-methoxy isomers determined by Fourier Transform Raman Spectroscopy wherein the ratio is a fixed ratio from about 5% or less of the 5-methoxy isomer and from about 95% or more of the 6-methoxy isomer.

The examiner disagrees with the above argument. As evidenced by the applicant's own admission (page 5, lines 6-7 and page 18, lines 10-14 of the specification), the omeprazole or commercially available Prilosec contains 5-methoxy and 6-methoxy isomers in 7:93 \pm 2%. Although it was not previously known that the omeprazole or commercially available Prilosec contains not only 5-methoxy isomer but also 6-methoxy isomer, applicants' discovery of new 6-methoxy isomer inherently presented in the old composition fails to confer patentability to an old composition. Therefore, the reference anticipates the claimed invention.

Conclusion

8. The applicant's amendment necessitated a new ground of rejection in this Office Action. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

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will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

9. No Claim is allowed.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Kwon whose telephone number is (571) 272-0581. The examiner can normally be reached Tuesday through Friday from 9:00 am to 7:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, can be reached on (571) 272-0951. The fax number for this Group is (703) 872-9306.

Any inquiry of a general nature of relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.



Brian Kwon
Patent Examiner
AU 1614



VICKIE KIM
PRIMARY EXAMINER